

### Remarks

Claims 1, 3, 6, and 8-12 are pending in the application. By this amendment, Applicants have amended Claim 10. Claims 1, 3, 6, and 8 -12 remain pending. Claims 1, 11, and 12 are independent.

The present invention pertains to a method for inducing analgesia without anesthesia for treating non-neuropathic pain. Non-neuropathic pain suitable for treatment according to the invention includes pain associated with sprains; strains; soft-tissue injury (bruises and the like); repetitive motion injury; carpal tunnel syndrome; injury to tendons, ligaments, and/or muscles; conditions such as fibromyalgia, bursitis, castrochondritis, myofascial pain, and pain associated with arthritis, inflammation, contusions, post-surgical pain, and nociceptive pain. According to the method, lidocaine is applied via a transdermal patch applied on or adjacent the locus of the pain.

#### Claim rejections under 35 USC § 112

Claim 10 has been rejected under 35 USC § 112 “as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection stems from the limitation “said neuropathic pain” in the first line of the claim. This limitation has been amended to read “said non-neuropathic pain” and is now consistent with Claim 1, from which this claim depends. Accordingly, applicants believe this rejection has been obviated and respectfully request that it be withdrawn.

#### Claim rejections under 35 USC § 102(b)

Claims 1, 3, 6, 8, 9, 11, and 12 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,411,738 to Hind. This rejection is respectfully traversed. As stated in the rejection, "The Hind patent teaches methods and compositions for reducing pain from shingles by topical administration of lidocaine at a dosage below that which achieves analgesia without inducing anesthesia or systemic side effects." Applicants agree with this

assessment, but respectfully point out that shingles (or post-herpetic neuralgia) is neuropathic pain. In fact, as the first sentence of the Summary of the Invention, Hind states, "Methods and compositions are provided for safely reducing nerve injury pain from shingles (herpes zoster and post herpetic neuralgia) and analogous neuropathies," clearly indicating that these are neuropathic conditions. Thus the teachings of Hind fall squarely outside the scope of the claims of the present application, which is limited to the treatment of non-neuropathic pain.

#### Claim rejections under 35 USC § 103

Claims 1, 3, 6, 8, 9, 11, and 12 have been rejected under 35 U.S.C. § 103(a) over Hind. Claim 10 has been rejected under 35 U.S.C. § 103(a) over Hind in view of United States Patent No. 5,885,597 to Botknecht et al. Regarding the application of Hind to the claims of the present invention, Applicants refer to the argument presented above, that Hind is directed to neuropathic pain and the claims of the present application are limited to the treatment of non-neuropathic pain. Applicants respectfully suggest that Hind is thus inapplicable to the claims of the present application, whether under 35 U.S.C. § 102(b) or 35 U.S.C. § 103(a), and respectfully request that this rejection be withdrawn.

As to the rejection of Claim 10, the Action states, "It is the position of the examiner that one of ordinary skill in the art, at the time the claimed invention was made, would be motivated to use the compositions and methods of treatment of Hind to treat the joint disorders described in Botknecht *et al.*, in place of the compositions of Botknecht *et al.*, with a reasonable expectation of success." Applicants respectfully disagree with this position. It is Applicants' position that neuropathic and non-neuropathic (including nociceptive and somatic) pain are different in mechanism, symptoms, and treatment, and that one skilled in the art would have no expectation of success in taking an effective treatment for one type of pain and attempting to use it to treat the other type.

In support of Applicants' position, Applicants submit herewith the following three documents: Galer et al., Development and Preliminary Validation of a Pain Measure Specific to Neuropathic Pain: The Neuropathic Pain Scale, Neurology, Vol. 48, February 1997, pp332-338;

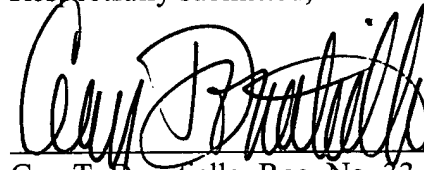
Vecht, et al., Symptomatic Management of Nerve Pain, presented at the 4<sup>th</sup> Annual Conference on the "Mechanisms & Treatment of Neuropathic Pain," September 20, 2001; and Galer et al., Response to Intravenous Lidocaine Infusion Differs Based on Clinical Diagnosis and Site of Nervous System Injury, *Neurology*, Vol. 43, June 1993, pp1233-1235. The documents generally distinguish neuropathic and non-neuropathic pain, and their causes and treatments.

It may be useful to note that Vecht et al. sets forth compounds commonly used to treat neuropathic pain. Vecht states that "the most effective drugs for neuropathic pain," are tricyclic antidepressants. Other compounds set forth by Vecht include anticonvulsants, such as phenytoin and gabapentin, mexiletine, intravenous lidocaine, dextromethorphan, baclofen, opioids, clonidine, capsaicin, and ketamine. Of these, the only traditional analgesics are the opioids which is fewer than one in ten of the compounds or classes noted to have effect against neuropathic pain. Notably absent are other traditional analgesics, such as NSAIDs, acetaminophen, COX-2 inhibitors, etc. Thus, the drugs which are effective against neuropathic and non-neuropathic pain tend to be totally different classes. Accordingly, Applicants respectfully submit that the chance of a drug, effective against neuropathic pain, having an effect against non-neuropathic pain is such that one of ordinary skill in the art would not form a reasonable expectation that a substance showing action against neuropathic pain would therefore be effective against non-neuropathic pain. Thus, Applicants respectfully request that this rejection be withdrawn, or some evidence offered to show that "one of ordinary skill in the art, at the time the claimed invention was made, would be motivated to use the compositions and methods of treatment of Hind to treat the joint disorders described in Botknecht *et al.*, in place of the compositions of Botknecht *et al.*, with a reasonable expectation of success."

Finally, Botknecht *et al.*'s use of lidocaine is as an anesthetic. At Column 5, lines 46 – 65, Botknecht suggests the p-aminobenzoic acid ester type local anesthetic counteracts the irritating effect of capsaicin, and that, "in the composition of this invention [the capsaicin] is unexpectedly well tolerated ....

Applicants respectfully submit for the reasons set forth above, the claims as amended are patentable over the applied references. Accordingly, early reconsideration and allowance of all pending claims is respectfully requested.

Respectfully submitted,



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enclosures:

Galer et al., Development and Preliminary Validation of a Pain Measure Specific to Neuropathic Pain: The Neuropathic Pain Scale, Neurology, Vol. 48, 2/97, pp332-338.  
Vecht, et al., Symptomatic Management of Nerve Pain, presented at the 4<sup>th</sup> Annual Conference on the "Mechanisms & Treatment of Neuropathic Pain," September 20, 2001.  
Galer et al., Response to Intravenous Lidocaine Infusion Differs Based on Clinical Diagnosis and Site of Nervous System Injury, Neurology, Vol. 43, June 1993, pp1233-1235.

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7 March 2003

